DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

January 8, 2001

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 01-15

Michael J. Clark, Owner
C&H Classic Smoked Fish
28 Howard Road
Cathlamet, Washington 98612

WARNING LETTER

Dear Mr. Clark:

We inspected your firm located at 28 Howard Road, Cathlamet, Washington, on September 6, 2000, and found you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to you at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your vacuum packaged hot smoked salmon products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations are as follows:

1. You must take an appropriate corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). Your firm did not take a corrective action to control *Clostridium botulinum* toxin formation when your process for vacuum packaged hot smoked salmon deviated from your critical limit at the brining critical control point. [redacted] batches of hot smoked salmon were produced between April 14, 2000 and September 3, 2000. Your HACCP plan lists a critical limit of [redacted] for the brining time, however, monitoring records document a brining time of [redacted] for these [redacted] batches, yet no corrective action was taken.

2. You must include in your HACCP plan how you are controlling for *Clostridium botulinum* toxin formation in your smoked product, to comply with 21 CFR 123.16. Critical limits must be established that relate to elements of your process that affect the level of water phase salt (WPS) in your finished product. You must achieve either 3.5% WPS or 3.0% WPS in

combination with 100-200 ppm nitrite. The adequacy of your critical limits must be verified to assure that they can consistently be achieved. Results of our sample analysis of ten subsamples showed variable WPS levels ranging from 2.49 to 4.47% WPS. This variation indicates a failure to properly control at the brining critical control point.

3. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). Your firm did not record monitoring observations at the cooler storage critical control point to control *Clostridium botulinum* listed in your HACCP plan for vacuum packaged hot smoked salmon. The Cooler Storage Log includes no temperature recordings for the period June 14, 2000 through September 3, 2000. Hot smoked salmon was produced during this time period.

Chapter 13 of the Fish & Fisheries Products Hazards & Controls Guide, Second Edition, gives thorough information on the biological hazard of *Clostridium botulinum* toxin formation. We suggest you consult the Guide to better understand this hazard, and how it should be controlled. This guide can be located through links in FDA's homepage at www.fda.gov.

Labeling:
The Food and Drug Administration also reviewed your labels for vacuum packaged hot smoked salmon. The FDA investigator collected the labels during the inspection of your firm. Our review reveals that these labels cause the products to be in violation of Section 403 of the Act, and Title 21, Code of Federal Regulations (21 CFR), Part 101 - Food Labeling, as follows:

1. The product is misbranded in that it fails to bear nutritional labeling as required under Section 403(q)(1) of the Act, and 21 CFR 101.9, and is not exempt under Section 403(q)(5) from this requirement, and has been labeled on or after August 8, 1994. Some small businesses are exempt from nutritional labeling requirements. Businesses must file an annual notice with FDA that they are claiming an exemption. A Small Business Food Labeling Exemption Notice, which includes exemption criteria and instructions on filing an exemption notice, is enclosed. A copy of A Food Labeling Guide, which contains applicable sections of the food labeling regulations, is also enclosed for your review.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

For your information, our investigator also noted that your HACCP plan does not list the food safety hazard of allergens. Our investigator's observation of the use of FD&C Yellow #5 Lake in your salmon products without declaration on your labels resulted in your voluntary recall of the affected products. Controlling the hazard of allergens is typically accomplished by listing label review as a critical control point in the HACCP plan.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Althar at (425) 483-4940.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR Part 123
Section 402 of the Federal Food, Drug, and Cosmetic Act
A Food Labeling Guide
A Small Business Food Labeling Exemption Notice

cc: WSDA with Disclosure Statement